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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/517,645

Applicant(s)

PRIGENT ET AL.

Examiner

Lynn Bristol

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-19, 21 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/10/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Claims 1 and 14-25 are all the pending claims for this application.
2. Applicants preliminary amendment to the specification of 12/10/04 to cross-reference the priority documents has been entered.

Election/Restrictions

3. Applicant's election without traverse of Group I (Claims 1, 14, 20 and 22) in the reply filed on 6/29/07 is acknowledged.
4. Claims 15-19, 21 and 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions of Groups II-V, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/29/07.
5. Claims 1, 14, 20 and 22 are all the pending claims under examination.

Information Disclosure Statement

6. The U.S. and international patent references and the non-patent literature references cited in the IDS of 12/10/04 have been considered and entered.

Specification

7. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.

Applicants are requested to insert section headings into the specification where appropriate as outlined above. The Brief description of the Figures occurs on pp. 15-16 of the instant specification and should be inserted between the Summary and Detailed Description sections of the specification.

Claim Objections

8. Claims 1, 14 and 20 are objected to because of the following informalities:

- a) Claim 1 is objected to for reciting "*" to designate the specific properties of the Mab and "-" to designate the steps for the process of obtaining the Mab. Reciting the

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separate properties of the Mab by alphabetical numeration (e.g., a) -d)) and the separate steps for producing the Mab by numerical designation (e.g., 1) -7)) would clarify the description of the product-by-process claim. Further, Applicants may wish to distinguish the process steps by creating a "wherein" clause for the phrase "said monoclonal antibody being obtained by".

b) Claim 1 is objected to for the language "it" in lines 3, 4, 6 and 7, and the term can be substituted with "the antibody", for example.

c) The recitation "fusion between cells of the spleen of these mice and hamster cells" in Claim 1, line 12, could be more clearly written as "fusing spleen cells of said mice with hamster cells...", for example.

d) Claim 1, line 8, recites "being as obtained by" and the term "as" does not modify or define the phrase.

e) The recitation "also called 35C1 antibody, as secreted by..." in Claim 14, lines 1-2, could be more clearly written as "wherein the antibody is the 35C1 antibody secreted by...", for example.

f) Claim 20 is objected to for depending on a non-elected claim, Claim 18. Claim 20 could be rewritten as a kit comprising the recited elements without intended use language.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 14, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1, 14, 20 and 22 recite the limitation "the membranes" in Claim 1.

There is insufficient antecedent basis for this limitation in the claim.

b) Claims 1, 14, 20 and 22 recite the limitation "the human or murine aurora-A protein" in Claim 1. There is insufficient antecedent basis for this limitation in the claim which recites "human and murine aurora-A kinase" in the preamble.

c) Claims 1, 14, 20 and 22 are indefinite for the recitation "and, if appropriate, purification" because it is not clear what conditions are appropriate for purifying the protein with the antibody. Alternatively, if purification is an option, then inserting "optional" language may clarify the intended meaning.

d) Claims 1, 14, 20 and 22 are indefinite for the recitation "produced by E. coli bacteria transformed with a bacterial expression vector in the genome of which the human cDNA coding for aurora-A has been inserted" in Claim 1, because it is not clear whether the "genome" refers to the vector construct or the genome of the bacterium. Or is the entire expression vector required to integrate into the genome of the bacterium?

e) Claims 1, 14, 20 and 22 are indefinite for the recitation "the preceding stage" in lines 16, 18, 22, 26, 30 and 34 of Claim 1, because it is not clear what the meaning is

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for a "stage" in performing the process steps. Further or alternatively, the phrase "the preceding stage" lacks antecedent basis. Still further, it is not clear which of the steps in obtaining the Mab necessarily precedes any other step in performing the process. For example, once the hybridoma has been produced, is one of skill in the art required to perform the subsequent process steps in a precise order in order to positively select the hybridoma?

f) Claims 1, 14, 20 and 22 are indefinite for the recitation "possessing all of the properties defined above" in Claim 1, because it is not clear if the properties referred to are those set forth in lines 3-7 of Claim 1, or the properties in lines 3-7 in addition to the implied properties as set forth in the hybridoma screening steps of the remainder of the claim.

g) Claim 20 is indefinite for the recitation "the PCNA protein" because it is not clear what the intended protein is in the universe of proteins. The description of the protein is incorporated by reference on p. 3, lines 29-32 of the specification.

h) Claim 20 is indefinite for the recitation "if appropriate, a cell proliferation marker" because it is not clear when or under what conditions the anti-PNCA antibody should be included for use. Alternatively, if including the anti-PNCA antibody is an option, then inserting "optional" language may clarify the intended meaning.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit Requirement

10. Claim 14 is rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (a) known and readily available to the public; (b) reproducible from the written description.

a. It is unclear if a cell line, which produces an antibody having the exact chemical identity of 35C1, is known and publicly available, or can be reproducibly isolated without undue experimentation. P. 3, lines 17-20 in the specification identify the date of deposit, the depository and assigned deposit number for the hybridoma producing the 35C1 monoclonal antibody, but the specification does not verify compliance under the Budapest Treaty or make any assurances of the terms and conditions for releasing the clone upon issuance of a patent or for maintaining the clones during the patent term.

Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid

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sequence is an unpredictable event.

b. For example, very different V_H chains (about 50% homologous) can combine with the same V_K chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_K sequences to produce antibodies with very similar properties. The results indicate that divergent variable region sequences, both in and out of the complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. [FUNDAMENTAL IMMUNOLOGY 242 (William E. Paul, M.D. ed., 3d ed. 1993), p. 1]. Therefore, it would require undue experimentation to reproduce the claimed antibody species 35C1. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty,

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then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to

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corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37.CFR 1.801-1.809 for further information concerning deposit practice.

Priority

11. The priority claim to PCT/FR03/01772 (filed 6/12/03) for the 35C1 monoclonal antibody is acknowledged. Applicants have not provided a certified translation of the French language priority document, FR 02/07212, filed 6/12/2002 to verify whether Claims 1, 14, 20 and 22 and all of the recited limitations obtain benefit of the foreign filing date 6/12/2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1, 14, 20 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Cremet et al. (Molec. & Cell. Biochem. 243:123-131 (2003); cited in the IDS of 12/10/04) as evidenced by the HyCult Biotechnology datasheet for 35C1 (p. 1, 2/2004).

The interpretation of Claim 14 is discussed supra. Claim 1 is interpreted as being drawn to a Mab recognizing both human and murine aurora-A kinase having the properties of: binding to membranes containing the human or murine protein, detecting and purifying the human and murine proteins by immunoprecipitation, staining biological tissues where the protein is secreted, and does not inhibit the enzymatic activity of the protein, and where the antibody is obtained by: 5 injections of mice over a period of 15 days with a recombinant protein produced by E. coli bacteria transformed with an expression vector comprising the cDNA insert for human aurora-A and sacrificing the mice to obtain spleen cells for fusion to immortalized hamster cells to obtain hybridomas, followed by screening the hybridomas performing the following sequential steps: immunoprecipitating the recombinant protein, immunoprecipitating endogenous aurora-A protein from an extract of human HeLa cells, performing indirect immunofluorescence on the centrosomes and poles of the mitotic spindle of human cells in culture, immunoprecipitating endogenous aurora-A protein from an extract of

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murine cells in culture, performing indirect immunofluorescence on the centrosomes and poles of the mitotic spindle of murine cells in culture, and recovering and purifying the hybridoma possessing all of these properties. The indefiniteness of Claim 20 is discussed supra, but for purposes of citing prior art, the claim is interpreted as being drawn to a kit comprising the monoclonal antibody and (optionally, a marker for PCNA protein such as an anti-PCNA antibody). Thus, the inclusion of a marker for PCNA is not a required element of the kit. Claim 22 is interpreted as being drawn to a pharmaceutical composition comprising the monoclonal antibody.

Cremet discloses producing the 35C1 monoclonal antibody from a hybridoma produced by transforming *E. coli* with an expression construct containing the human cDNA encoding aurora-A (Materials & Methods, p. 124, Col. 2-3, ¶2) where the Mab is selected for: its binding to aurora-A at an epitope within a non-catalytic domain (Figure 3A), binding to human and murine Aurora-A kinase protein based on its ability to detect the human and mouse protein by Western blot (Figure 2, 4a, lane 2), binding to human (HeLa) and mouse cell extracts (Figure 4a) and spindle poles in both human and mouse cells indirect immunofluorescence detection (Figure 4b), immunoprecipitation of the protein from human cell extracts (Figure 8). The ability of the 35C1 antibody to immunoprecipitate an endogenous aurora-A protein from a murine cell extract would have been inherent to the antibody. Cremet discloses using the antibody as a tool for human tumor prognostics (p. 124, Col. 1, ¶4), using the antibody in animal models of human pathologies (p. 130, Col. 1, ¶2), and using the antibody to screen a large number of different human cancers where the level of kinase is determined by Western

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blots, kinase activity, overexpression of the protein in tissues based on immunodetection of heterogeneous cells and the number of centrosomes counted. The multiple intended uses of the 35C1 antibody disclosed by Cremet for diagnostics and prognostics would have allowed one of skill in the art to readily provide the antibody as a pharmaceutical composition or in a kit as evidenced by the HyCult Biotechnology datasheet for 35C1. For all of these reasons, Cremet as evidenced by HyCult Biotechnology read on and therefore anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
13. Claims 1, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honda et al. (Oncogene 19:2812-2819 (2000)) as evidenced by Giet et al. (J. Cell

Sci. 114: 2095-2104 (2001) and Shindo et al. (Biochem. Biophys. Res. Comm. 244:285-292 (1998)) in view of Bischoff et al. (Trends Cell Biol. 9:454-459 (1999)).

The interpretation of Claims 1, 20 and 22 is discussed supra. The product-by-process of Claim 1 is not limited to the manipulations of the recited steps, only the structure implied by the steps (MPEP 2113), therefore the claims are examined for the product of an anti-aurora A monoclonal antibody having the properties set forth in lines 3-7 of the claim.

The claimed anti-aurora-A (or aurora 2) antibody would have been prima facie obvious at the time of the invention in view of Honda as evidenced by Giet and Shindo, and Bischoff.

Honda discloses an aurora2 (aurora A) monoclonal antibody (M11-17) recognizing an epitope in the N-terminal domain of human aurora A (p. 2813, col. 2, ¶1; p.2816, col. 2, ¶1), that recognized lysates from COS cells transfected with aurora A (figure 1a) and HeLa cells (figure 1b) in a Western blot, localized to the centrosome and spindle pole region in HeLa cells by immunofluorescence microscopy (figure 1c) and immunoprecipitated aurora from HeLa and transfected COS cells (figure 2b). The monoclonal antibody of Hondo binds a single N-terminal epitope, which does not effect the binding site of the protein to spindle fibers as shown by the immunofluorescence data. As evidenced by Giet and Shindo, the catalytic site and the spindle-binding site for the family of aurora2 (aurora A) proteins are not overlapping. Geit teaches that the N-terminus is the non-catalytic domain, thus one skilled in the art would not expect the monoclonal antibody of Hondo to inhibit the enzymatic (kinase) activity of the protein.

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Honda does not specifically disclose that the monoclonal antibody is cross-reactive with murine aurora2 protein (aurora A) much less the N-terminus, but in view of the shared homology between the human and murine N-terminal amino acids for the sequences as evidenced by Shindo (Figure 1A and Figure 2, comparing human, mouse and *Xenopus*), one skilled in the art would readily envisage that the M11-17 Mab possessed the inherent ability to bind the murine aurora2 (aurora A) protein at the time of the invention (see *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977)). Although Hondo does not specifically disclose kits and pharmaceutical compositions comprising the antibody, what is implicit in the use of the M11-17 Mab by Hondo (e.g., immunostaining, immunoblotting and immunoprecipitating the aurora2 (aurora A) protein) are applications for diagnosing cancerous cells such as HeLa cells.

Bischoff reviews the role of the family of aurora2 (aurora A) proteins in examining cell cycle progression especially in some cancers where the protein has been identified as an oncogene (p. 457-458), and the possibility of targeting aurora2 (aurora A) for therapeutic development.

One skilled in the art would have been motivated and been reasonably assured of success in having produced the claimed anti-aurora A antibody based on the combined disclosures of Honda as evidenced by Giet and Shindo, and Bischoff. Honda discloses an anti-aurora A monoclonal antibody that could be used to immunostain, immunopurify and/or immunoblot the human aurora A protein expressed in a transfected COS cell and a human HeLa cell. Notably the antibody was selected from amongst five hybridomas for its ability to detect the aurora A protein binding to spindles

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in the centrosomes of replicating cells, and thus the specificity of the antibody was not for the catalytic site of the protein but for an epitope in the N-terminal domain that would not effect or impair its enzyme activity or spindle-binding activity as evidenced by Geit and Shindo. The motivation to identify an antibody with these properties would have been obvious in order use the antibody in cancer diagnosis as taught by Bischoff explicitly, and by Hondo implicitly. The antibody design would allow one of skill in the art to use the antibody to count centrosomes, for example, and to design drug inhibitors for the kinase portion of the aurora protein. One skilled in the art would have been reasonably assured of producing an antibody as claimed because antibodies reading on the instant claims had already been produced by Honda and been shown to have practical utility as a diagnostic.

The product-by-process of Claim 1 is not limited to the manipulations of the recited steps, only the structure implied by the steps (MPEP 2113), therefore the claims are examined for the product of an anti-aurora A monoclonal antibody having the properties set forth in lines 3-7 of the claim. For all of the foregoing reasons, the claims were prima facie obvious at the time of the invention over Honda as evidenced by Giet and Shindo, and Bischoff.

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Conclusion

14. No claims are allowed.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883.

The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER